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**CIVIL LAW REGULATION AND PROTECTION OF GENES  
AND GENOMIC TECHNOLOGIES: PROBLEMS OF THEORY AND PRACTICE**

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**Abstract:** Currently, both law enforcement activities and dynamically developing legal regulation are aimed at the involvement of genes and genetic structures in civil circulation. The civil-legal direction is actively developed in order to ensure the defense of genes and the realization of the rights and obligations of subjects of bio-medical technologies in the field of genes of genomic structures in civil-legal relations.

Especially a large number of questions and difficult from a civil point of view of practical problems arise in determining the possibility of including genes and genomes in the list of objects of civil rights, their turnover.

The article defines some areas of civil regulation of genomic technologies in modern Russia, the qualification of genes and genomes as objects of civil relations, the turnover of genes and genetic structures.

**Key words:** Genes, genome, turnover capacity, objects of civil rights, things, genetic technologies, civil turnover, civil law regime.

Undoubtedly, human life is the highest value in any modern civilised society. Article 17 of the Russian Constitution stating: “fundamental human rights and freedoms are inalienable and belong to everyone from birth” is related to the definition of the beginning of a child’s life<sup>1</sup>. Only a physically, genetically and mentally

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<sup>1</sup> Constitution of the Russian Federation (adopted by a nationwide vote on 12.12.1993) (with amendments introduced by the Federal Law of the Russian Federation On Amendments to the

healthy man and woman can create a healthy family not transferring the burden of serious illness to their partners and future children.

At the present stage of formation of the rule of law and a developed civil society in the Russian Federation, the possibility of using genes, genomes and genomic technologies, which seem to belong mainly to the private life of citizens, in civil turnover and civil law protection is of particular relevance.

We are convinced that at the present stage of formation of the rule of law and developed civil society in the Russian Federation, the possibility of using genes, genomes and genomic technologies and constructs in civil circulation and their civil legal protection, relating mainly to the sphere of civil law regulation, is of particular relevance. At present, quite a number of scientific and practical researches and experiments of medical and civil nature aiming at involving genes and genetic constructions in civil legal relations as objects of civil rights are being carried out. The question arises, therefore, as to the civil law capacity of genes and genetic constructions.

It is necessary to state that a scientific trend has already been formed in the world with the practical purpose of gene editing. The medical practice of introducing such developments is aimed at realising the genetic “improvement” of human life and health. Society has been in the age of genetic engineering for quite some time.

We believe that awareness of the need for civil law regulation of genetic engineering activities in relation to the human body and protection of rights in the field of genomic technologies has come to the Russian legislator only in recent years, that is, quite recently, due to the rather rapid development of genomic technologies, genetic engineering in the Russian biomedical practice.

The importance of the development of competitive civil law turnover, including social and legal relations, such as biomedical activities and genetic engineering is increasing every year. Healthy competition, free entrepreneurship, and the involvement of more and more objects in civil turnover are the most important factors in the development of civil legal relations in modern Russia, the sustainability of the national economy, and the protection of intellectual rights in the field of biomedicine and genomic research.

A particularly large number of questions and practical problems arise in determining whether genes and genomes can be included as objects of legal relations and defined as objects of civil rights.

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Constitution of the Russian Federation dated 30.12.2008 No. 6-FKZ, dated 30.12.2008 No. 7-FKZ, dated 05.02.2014 No. 2-FKZ, dated 21.07.2014 No. 11-FKZ) // Russian Federation Code. 2014. No. 31. Article 4398.

The search for the most optimal model of relations between the individual, government and society inevitably depends on a scientifically grounded solution of a set of problems in the field of genetic engineering and genomic technologies, which for a long time have not found a uniform resolution both in doctrine and in law enforcement of medical activity. One of these important problems is the definition of the civil law regime for genes.

Medical activity is a type of professional activity, which results in a relationship between a medical organisation (health worker) and a patient. “When seeking medical care, a person quite often has to disclose certain aspects of his or her private and family life to the doctor, and in the process of providing this very care the doctor becomes aware of the person’s illnesses, past procedures and other medical features”<sup>1</sup>.

The right to health protection is enshrined in the provisions of the Constitution of the Russian Federation<sup>2</sup>. In furtherance of the provisions of the Basic Law, relevant legislative acts have been adopted which are aimed at protecting the health of citizens and the development of genomic technologies, genetic engineering and biomedicine.

The necessity and practical significance of the study of genes, not only from a biological point of view, but also from a legal and civil point of view, is determined by the fact that a gene may directly affect the presence of a trait (phenome) of an organism or take part in the formation of several traits, forming a specific genetic construction, which is involved in civil law relations and becomes an object of civil rights<sup>3</sup>.

The importance of developing competitive civil law turnover, including those in social and legal relations such as biomedical activities and genetic engineering, is growing every year. Healthy competition, free entrepreneurship, and the involvement of more and more objects in civil turnover are the most important factors in the development of civil legal relations in modern Russia, the sustainability of

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<sup>1</sup> Levushkin A. N., Pushkareva A. N. *Publichnyi dogovor ob okazanii platnykh meditsinskikh uslug i zashchita vrachebnoi tainy: teoriia i praktika primeneniia* [Public contract for the provision of paid medical services and protection of medical secrecy: theory and practice of application] // *Grazhdanskoe pravo = Civil right*. 2016. No. 3. P. 14. (In Russian).

<sup>2</sup> Constitution of the Russian Federation (adopted by a nationwide vote on 12.12.1993) (with amendments introduced by the Federal Law of the Russian Federation On Amendments to the Constitution of the Russian Federation dated 30.12.2008 No. 6-FKZ, dated 30.12.2008. No. 7-FKZ, dated 05.02.2014 No. 2-FKZ, dated 21.07.2014 No. 11-FKZ) // *Russian Federation Code*. 2014. No. 31. Article 4398.

<sup>3</sup> See: Levushkin A. N. *Grazhdansko-pravovoe regulirovanie genomnykh tekhnologii i oborotosposobnost' genov kak ob'ektov grazhdanskikh prav* [Civil law regulation of genomic technologies and gene turnover as objects of civil rights] // *Grazhdanskoe pravo = Civil right*. 2019. No. 5. P. 26–29. (In Russian).

the national economy and the protection of civil, intellectual rights in the sphere of biomedicine and genomic research.

According to Article 8 (1) of the Constitution of the Russian Federation, the Russian Federation guarantees the unity of the economic space, the free movement of goods, services and financial resources, support for competition and freedom of economic activity.

“Only a physically, genetically and mentally healthy man and woman can create a healthy family not transferring the burden of serious illness to their partners and future children. The rapid pace of modern life does not always provide opportunities for routine health check-ups for certain segments of the population”<sup>1</sup>.

We believe that at present, given the development of civil and medical legislation, there is an objective need to qualify and define the legal nature of genes and genomes as objects of civil rights and to establish a special civil law regime for genes, genomes and genetic constructions. This special civil law regime for genes should have a special civil law nature. Genes can be qualified as objects of civil rights and their negotiability can be determined based on this formulation of the question<sup>2</sup>.

We are convinced that at the current stage of legal regulation of genetic engineering activities of genes and genomes use, the public law performs such a new function of protecting the rights of citizens as ensuring their private interests in genetic engineering and involvement of genes in the civil turnover. Achieving a balance of public and private law in the regulation of relations arising from the involvement of genes in civil circulation, establishing a regulatory framework for genetic engineering in the Russian Federation is both an objective and a necessary condition aimed at the further development of biomedicine, human health and life, strengthening and implementing the system of citizens' rights in the sphere of biomedicine in any modern society, especially in our country at the present stage.

It is worth agreeing with the doctrine's suggestion that a Federal Law On Government Regulation of Genetically Engineered Activities in relation to Human Beings should be adopted. As G. B. Romanovsky not unreasonably suggests, the said regulatory act should establish general principles of respect for human rights, as well as a number of bans: forced genetic counselling; commercial use of genetic material; genetic screening of the entire population; systematisation of genetic

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<sup>1</sup> *Levushkin A. N. Pravovye aspekty meditsinskogo obsledovaniia lits, vstupaiushchikh v brak, v stranakh SNG* [Legal aspects of medical examination of persons entering into marriage in the CIS countries] // *Meditsinskoe pravo* = Medical law. 2011. No. 3. P. 41. (In Russian).

<sup>2</sup> See: *Levushkin A. N. Grazhdansko-pravovoi rezhim genov kak ob'ektov grazhdanskikh prav* [Civil legal regime of genes as objects of civil rights] // *Lex Russica. Zakon russkii* = Lex Russica. The law of the Russian. 2019. No. 6. P. 100–109. (In Russian).

material in relation to Russian citizens by foreign organisations; and discrimination based on DNA information.

Strict government control over the collection of genetic information by foreign organisations, excluding joint activities between foreign and Russian scientific organisations, permitted under a specially established procedure.

Priority of public funding for scientific organisations engaged in human genetics research<sup>1</sup>.

Medical tourism is developing at a significant rate worldwide and a new type of similar activity, “gene tourism”, is spreading. There is genetic pluralism: cloning is banned in some countries but allowed in others; GMOs are banned from cultivation in some countries but allowed in others; labelling of GMO products is required in some countries; some countries experiment with human genome editing while it is banned in others. There is no reason to believe that the same will not be true of “improving” humans. This is not to say that tomorrow there will be countries where everything is allowed. However, some variation will emerge, it is already taking shape.

The necessity of establishing a special civil legal regime for genes as objects of civil rights has been determined, which is a combination of ways, methods and types of civil legal regulation of the use of genes and genomes, which characterise a special combination of interrelated permissions, prohibitions, positive obligations established for subjects of genetic engineering, genomic research and aimed at ensuring effective use of genes, genomes and genetic constructions in citizens.

Indeed, it is the genes that “endow” the modern human being with biological capabilities, and it is the genes that limit the potential capabilities of the individual. The genes and genomes we have provide us with our essence, our inclinations and our opportunities to realise ourselves. It should be recognised that human beings are biological beings, and genes are the boundaries of our capabilities. To a certain extent, a person’s genes and genotype are a person’s future destiny and a set of possibilities for further realization during their life.

There is currently a moratorium on the use of biomedical cell technologies for human cloning purposes in Russia (cloning of cells and organisms for research purposes and cloning of organs for transplantation and animals is permitted). At the same time, however, work is proceeding on the experimental gene editing of human embryos.

We believe that the prevailing challenge in the field of medicine, biomedicine and genomic technologies is to ensure the safe transfer of high-tech industries

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<sup>1</sup> See: *Romanovskii G. B.* Pravovoe regulirovanie geneticheskikh issledovaniy v Rossii i Germanii [Legal regulation of genetic research in Russia and Germany] // *Pravozashchitnik* = Rights defender. 2016. No. 2. P. 5. (In Russian).

in medicine and genomic research to locations with low labour and input costs, and to ensure the predominance of Western rights holders in developing country economies in promising markets for genomic technologies.

It is debatable whether genes, genomes, genetic constructions are negotiable and whether it is possible to make various civil transactions with them, and whether the subjects (participants/persons) of genomic technologies enter into binding and proprietary legal relations with genes. The possibility of including genes and genomes in the objects of intellectual property rights and ensuring their patent protection, establishment of legal protection procedures was proved.

A legal analysis of the dynamics of normative regulation of biomedicine and the processes of studying and using genetic engineering and gene use activities in the Russian Federation for scientific purposes allows us to speak about new trends in the development of biomedical and 'gene' legislation, in particular, not only about changes in traditional areas as biology, genetics and medicine, but also about the appearance of new institutes and sub-branches, changes in the structure of legislation regulating activities in the field of medicine, biomedicine and genetics, indicating a transformation of its entire system. The content and scope of regulation and the inclusion of genes and the genome in the legal space are undergoing significant changes. The trend towards expanding the subject of regulation of the 'gene industry' is being realised.

It must be recognised that, in fact, the world has been living in the era of genetic engineering, of genetic modification, for over half a century now, without, however, giving much thought to the significance of the ongoing genetic revolution. In the last twenty to ten years with the development of GMO technology, this trend has attracted a lot of attention. It is undoubtedly objectively impossible to slow down and even more so to stop the spread of genetic technologies, the involvement of genes in civil turnover; genetic engineering is entering a new round of its high-tech development.

It has been established that, unfortunately, the awareness of the need for legal regulation of genetic engineering activities in relation to the human body has come to the Russian legislator just in the last decade, which is associated with a rapid development of doctrine in the field of genetic engineering and genomic research. This explains the backwardness of our government in the development of scientific ideas in the field of genomic research and the implementation of their results in medical practice.

Activities in the field of genomic research, the level of doctrinal and practical research in this field and the application of genetic technologies in the law enforcement process are mainly carried out by legal entities engaged in scientific, innovative, medical and some other activities in the implementation of various genetic engineering projects. For some of them the law already establishes higher require-

ments<sup>1</sup>. It seems that the greatest legislative and practical interest is the problem of qualification of genes as objects of legal relations, in general, and objects of civil rights, in particular, formation of the civil legal regime of genes.

It should be particularly noted that the problem of determining the objects of civil rights and civil legal relations has a rather long history of reflection in civil law doctrine. Indeed, the correlation between the categories of object of rights and object of legal relations is still debatable; what should be considered as the direct object: material and spiritual goods and rights or the actions and behaviour of persons.

Based on the analysis of law enforcement activities, it can be concluded that today it is quite important to resolve the situation and issues regarding the possibility and expediency of referring genes to the objects of civil rights and the formation of a special civil legal regime of genes and genomes, determining its content, implementing a mechanism for the protection of genes and genetic constructions. Accordingly, there is a question of formation of special civil legal regime of genes and genomes. Based on the current level of science and technology development, we believe that it is justified to refer genes to one of the objects of civil rights specified in Article 128 of the Civil Code of the Russian Federation. Such a conclusion can be based on the legal analysis of the category of genes and genome and the definition of the essence of these phenomena.

The concept of forming a civil society and constitutional state in Russia, and the effective development of medical services, where the protection of human rights and freedoms and the social and material wellbeing of people are of paramount importance, predetermine an increased scientific interest in the problem of taking into account the interests and protection of the rights of unborn children in civil turnover and medical practice.

The consideration of the interests and rights of unborn children in medical practice and civil relations must be seen in the context of reforming civil law<sup>2</sup>.

Most of the ideas concerning the development of the healthcare system, the expansion of the sphere of civil law services in biomedicine, genomic technologies are based on different methodological approaches, among which are the reorganisation and reform of the system of legislation regulating healthcare, genetic engineering,

<sup>1</sup> See: *Mokhov A. A. Dela o preduprezhdenii prichineniia vreda v budushchem (na primere genomnykh issledovaniy i vnedreniia ikh rezul'tatov v praktiku)* [Cases on prevention of harm in the future (on the example of genomic research and implementation of their results in practice)] // *Vestnik grazhdanskogo protsessa* = Bulletin of civil procedure. 2019. No. 2. P. 105. (In Russian).

<sup>2</sup> See: *Levushkin A. N. Nerodivshiesia deti: uchet interesov i prav v grazhdanskom oborote i meditsinskoj praktike* [Unborn children: consideration of interests and rights in civil circulation and medical practice] // *Zakony Rossii: opyt, analiz, praktika* = Russian laws: experience, analysis, practice. 2019. No. 6. P. 18–23. (In Russian).

optimisation of the structure and management of the sector, increased funding, development of biomedical technologies, improvement of civil law mechanisms for healthcare, improving the professionalism of doctors and geneticists in the use of genes, genomes in the delivery of biomedical services.

An important factor that should be noted is the implementation of priority areas for the further progressive development of healthcare in our country. This is certainly improving the quality of medical and biomedical services, which are rather multifactorial and complex phenomena that are at the intersection of the interests of the population and the government, medical organisations and government health agencies.

It can be concluded, not uncontroversially for the doctrine, that genes and genomes, being special intellectual property rights, primarily enter objects of civil rights, have a legal characteristic that distinguishes them from other types of objects as defined by Article 128 of the Civil Code of the Russian Federation.

Thus, as a result of the study, having identified genes and genomes as special objects of civil rights, it seems necessary to implement recommendations aimed at improving the protection of intellectual property rights in the field of providing special civil legal regime for genomes by applying a broader use of patent protection. It is patent protection that can confer monopoly rights on genes and genomes as specific intellectual property by granting patents on them as objects of intellectual work in biomedicine.

Genes and genomes have been shown to have a separate place amongst the subject matter of intellectual property rights or to be attached to one of the existing subject matter (with certain exceptions).

Article 60 of the Family Code of the Russian Federation establishes that every child has the right to parental support or persons in loco parentis. It appears that the right to support also applies to a child who has been conceived but not born. Among other things, Article 89 of the Family Code allows a wife during pregnancy to claim alimony from the other spouse in court.

We consider it justified to clarify Article 17 of the Civil Code of the Russian Federation in terms of the definition of a citizen's legal capacity, which arises from the moment of their birth if vital signs provided for by the medical rules are present.

Thus, in the course of the research work, some areas of civil law regulation of the implementation of genomic technologies in modern Russia, the qualification of genes and genomes as objects of civil legal relations, and the turnover of genes and genetic constructions were determined.

It is argued that at the present stage of legal regulation of genetic engineering of genes and genomes use, the public law performs such a new function of protecting the rights of citizens as ensuring their private interests in genetic engineering, involving genes in civil turnover. Achieving a balance of public and



private law in the regulation of relations arising from the involvement of genes in civil turnover, establishing a regulatory framework for genetic engineering in the Russian Federation is both an objective and a necessary condition aimed at the further development of biomedicine, human health and life, strengthening and implementing the system of citizens' rights in the sphere of biomedicine in any modern society, especially in our country at the present stage.

The main task of the Russian legislator is to establish a balance of public and private interests in the regulation of genetic engineering, implementation of genomic research and to achieve this balance by including genes and genomes as special objects of legal relations and civil rights.

The necessity of establishing a special civil legal regime for genes as objects of civil rights has been determined, which is a combination of ways, methods and types of civil legal regulation of the use of genes and genomes characterising a special combination of interrelated permissions, prohibitions, positive obligations established for subjects of genetic engineering, genomic research and aimed at ensuring effective use of genes, genomes and genetic constructions in civil turnover.

In modern civil turnover there is an objective need to qualify and determine the civil law nature of genes and genomes as objects of civil rights and to establish a special civil law regime of genes, genomes and genetic constructions. The possibility of legal regulation of genomic research and implementation of its results in medical practice in the provision of services of civil law nature is proved.

The possibility of including genes and genomes in intellectual property rights and providing for their patent protection and the establishment of legal protection procedures has been proven.

Thus, *de facto* humanity is already in the mode of its own genetic transformation and transformation of biosocial environment. Currently, there is an objective need to develop and justify new directions for improving the system of legislation of the Russian Federation, in general, and civil legislation, in particular, aimed at effective and objectively justified regulation of genes and genomes, the objects of genetic engineering, based on the goals of state policy in the field of biomedicine and the existing social and legal potential of genetic engineering practice development.

The civil legal regime for genes and genomic technology is inextricably linked to the right to human life, the provision of qualified medical care to a citizen, and the process of treating a patient, since any interaction between a person (patient) and a doctor, geneticist and other medical personnel gives rise to the right to health care. One of the aims of establishing a civil law regime for genes and genomes is to ensure that the legislator has proper legal regulation of their involvement and subsequent participation in civil transaction.

The special civil legal regime for genes is the possibility or impossibility of certain actions (transactions) with genes that are object, as well as the set of rights

and obligations, permissions and prohibitions associated with such actions of the various persons involved in the genetic engineering relationship.

The inclusion of specific objects such as genes in civil law inevitably involves the establishment of a fiduciary relationship between the parties involved in the use of genes and genetic technology in civil law.

The civil law regime of genes and the genome as objects of law is directly influenced by the legal characteristics of such objects (whether it is a property or another object, free in circulation or restricted, and so on). In turn, the social and legal characteristics of the object are influenced by the properties of the object as a phenomenon of reality<sup>1</sup>.

We consider it possible to take into account the interests and rights of unborn children in the civil sphere in the context of ensuring and protecting traditional family values based on the family and parent-child relationships.

The following peculiarities and essential substantive properties of special civil legal regime of genes are distinguished: 1) special basis of origin of such regime. Establishment of the special civil legal regime on genes is connected with rendering of professional medical aid and medical service in the sphere of genetic engineering to the citizen; 2) genes and genomes are special object, complex nature of substances and information included in genes and genomes; 3) inseparable and objective connection of genes with persons; 4) existence of such special persons as doctors, geneticists, biologists and medical personnel, who are obliged not to disclose certain information in genomic developments in connection with performance of their profession; 5) Ensuring the development of genetic engineering sphere by government coercive measures and possibility of application of civil and other legal responsibility, provided by norms of different branches; 6) Regulation on the basis of civil legal regulators and legislation norms in the sphere of medicine, moral injunctions, personal qualities.

It is argued that the special civil law regime of genes is of civil law nature. However, this legal regime is regulated by norms of constitutional, civil, business, administrative, medical law. The civil law regime of genes and genomes receives normative establishment both at the level of private law and public law regulation in order to ensure effective and harmonious protection of citizens' rights in the sphere of genetic engineering, implementation of genomic research and biomedicine.

It has been proved that the civil legal regime of genes and genomic technologies is inextricably linked to the right to human life, the provision of a citizen with qualified medical care, with the process of patient treatment, since any fact of

<sup>1</sup> See: *Levushkin A. N. Grazhdansko-pravovoi rezhim genov kak ob'ektov grazhdanskikh prav* [Civil legal regime of genes as objects of civil rights] // *Lex Russica. Zakon russkii = Lex Russica. The law of the Russian*. 2019. No. 6. P. 102. (In Russian).

interaction between a person (patient) and a doctor, geneticist and other medical personnel generates provision of the right to health protection. One of the aims of establishing a civil law regime for genes and genomes is to ensure that the legislator has proper legal regulation of their involvement and subsequent participation in civil turnover.

The result of this study is that the development and scientific understanding of genes and genetic engineering are closely related, and in some cases only within the medical activity (practice) in its broadest sense. Which seems very justified. Indeed, medical activity is one of the most important economic, practice oriented activities, which is of key importance not only to specific individuals who are the consumers of medical services, but also to society and the state<sup>1</sup>. Obviously, biomedical practice also has an important private and public, and social and legal character.

We are convinced that now there is an objective need to develop and substantiate new directions for improving the system of Russian legislation based on the goals of public policy aimed at the development of genetic engineering and the existing social and legal potential for biomedical development.

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<sup>1</sup> See: *Mokhov A. A. Meditsinskaia deiatel'nost' vid sotsial'nogo predprinimatel'stva* [Medical activity a type of social entrepreneurship] // *Meditsinskoe pravo = Medical law*. 2016. No. 1. P. 6. (In Russian).

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